

**TALKING POINTS  
SCIENCE ADVISORY BOARD'S REVIEW OF EPA'S  
DRAFT RISK ASSESSMENT AND POLICY GUIDE**

The panel's conclusions on the risk assessment can be described only as irrational. The members acknowledged that the data presented in the report do not support the conclusions made and they agreed with virtually every criticism of the documents made.

The SAB's recommendations now go back to the EPA -- and EPA will make revisions. The panel has requested an additional review of the risk assessment once revisions are complete. Given that the SAB has asked for a rewrite of virtually everything in the draft report except the conclusions, a re-review is essential.

In revising its risk assessment, EPA has said -- in recent Congressional hearings -- it will consider several studies published since the initial draft was completed.

- o The most recent ETS - lung cancer study to appear in the scientific literature -- a large case-control study of a population of Chinese women -- found no association between spousal smoking and lung cancer. In fact, the study reported a statistically significant inverse relationship between spousal smoking and lung cancer risk. Despite the fact that one of the members of the SAB committee which reviewed the ETS risk assessment was a co-author of the study, this research was never mentioned during the SAB's deliberations, nor was it provided for inclusion in the risk assessment's calculations.
- o When this and three other studies omitted by EPA are included in the Agency's meta analysis (the statistical procedure for combining the results of a number of studies to derive a single estimate of relative risk) -- using EPA's own method -- the results are not statistically significant. In other words, when the new studies are added, ETS exposure is not statistically associated with risk of lung cancer in nonsmokers.

The draft document is the first risk assessment ever conducted by EPA that is based entirely on epidemiologic evidence. The validity of the conclusions therefore depends entirely on the validity -- or lack thereof -- of this data. A review of the studies relied upon by the EPA reveals the following:

- o 24 studies are listed in the ETS report -- only five have reported a statistically significant association.
- o Of nine existing U.S. studies, none has reported a statistically significant association between spousal smoking and lung cancer in nonsmokers.

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During the review process, the SAB acknowledged that the existing report, based on flawed epidemiologic studies, did not adequately "make the case" that ETS is a cause of lung cancer in adults or respiratory effects in children.

Based on its "belief" that the conclusions are true however, the SAB recommended a number of revisions that it believes will bolster the case, including the instruction to analyze the data on mainstream smoking to prove that ETS must be harmful.

- o Such a suggestion disregards the fact that ETS and mainstream smoke are two different substances and different exposures.
- o This approach also disregards the report of the National Academy of Sciences which recognized qualitative and quantitative differences between ETS and mainstream smoke and raised doubts about the appropriateness of extrapolating to ETS from data on mainstream smoking.

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